Yamanouchi

Yamanouchi Pharma
Technologies, Inc.

Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304
T: 650.849.8505 F: 650.849.8565

January 11, 2001

To: Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: CITIZEN'S PETITION -- Suitability Petition for an Over-The-Counter (OTC) drug product, Famotidine Orally Disintegrating Tablets, 10 mg, docket number 00P-1422/CP 1

Dear Sir or Madam:

I am writing this letter regarding the referenced suitability petition requesting FDA's decision. The Dockets Management Branch of the Food and Drug Administration communicated to Yamanouchi Pharma Technologies, Inc. (YPT) in a letter dated July 20, 2000, assigning a docket number **00P-1422/CP 1** and filing date **July 19, 2000** to the referenced petition (Famotidine orally disintegrating tablets, 10 mg). In reviewing the OGD Suitability Petition Tracking Report posted on 10/12/2000 (page 37 of 83, copy attached), the filing date is listed as 8/3/2000 and approval of the petition is still pending. Enclosed please find copies of letters YPT received from the Food and Drug Administration regarding this subject (letter dated July 20, 2000, Dockets Management Branch of the Food and Drug Administration).

Please contact me to advise the status of the filing and regarding any questions or comments. Phone: 1-877-342-0895 (toll free) or (650) 849-8587, or by Fax: (650) 849-7887 or (650) 849-8622, or by E-mail: rkrishna@ypharma.com.

Sincerely,

Raan V. Krishna

Raan V. Krishna, Ph. D.
Manager, Regulatory Affairs

C1

00P-1422

Drug/Strength	*Petition No/ Firm*	*Dosage Form*	*File Date*	*Received*	*Reason For Petition*	*Decision*	*Status*	*Status Date*
ETHINYL ESTRADIOL 0.035 MG NORETHINDRONE 0.4 MG	99 P-1150/CP1 KIRKLAND & ELLIS	TABLET; CHEWABLE	4/27/99	5/11/99	NEW DOSAGE FORM	APPROVE	A	4/14/00
ETHINYL ESTRADIOL AND 0.05 M NORETHINDRONE 0.05 MG AND 0.05 MG AND 1 MG	84 P-0443/CP RW JOHNSON	TABLET; ORAL	1/8/85	1/13/85	NEW STRENGTH	DENIED	D	9/3/85
ETOPOSIDE 20 MG/ML, 25 ML	91 P-0041/CP ADRIA	INJECTION	2/4/91		NEW STRENGTH TOTAL DRUG CONTENT		A	5/22/91
ETOPOSIDE 20 MG/ML, 50 ML	91 P-0076/CP1 ADRIA	INJECTION	3/4/91		NEW STRENGTH TOTAL DRUG CONTENT		D	2/19/92
ETOPOSIDE 20 MG/ML, 50 ML PBP	91 P-0460/CP1 ABBOTT	INJECTION	11/20/91		NEW STRENGTH TOTAL DRUG CONTENT		A	2/11/93
ETOPOSIDE 25 MG OR 100 MG	92 P-0142/CP GUIDELINES	CAPSULE	3/20/92	3/20/92	NEW STRENGTH	APPROVE (25 MG)	A	9/12/96
ETOPOSIDE 20 MG/ML, 12.5 ML	92 P-0355/CP1 LEDERLE	INJECTION	9/11/92		NEW STRENGTH TOTAL DRUG CONTENT		A	1/7/93
FAMOTIDINE 10MG	00P-1422/CP1 YAMANOUCHI PHARMA TECHNOLOGIES	TABLET; ORALLY DISI	8/3/00	8/10/00	NEW DOSAGE FORM		P	
FAMOTIDINE 10 MG/ML (50 ML PB	97 P-0011/CP1 MARSAM PHARMACEUTICALS, INC.	INJECTABLE;INJECTI	1/14/97	2/3/97	NEW STRENGTH TOTAL DRUG CONTENT	APPROVE	A	6/10/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

RECEIVED
JUL 2 8 2000

July 20, 2000

Raan V. Krishna, Ph.D.
Yamanouchi Pharma Tecnologies Inc.
Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304

Dear Mr. Krishna:

Your petition requesting the Food and Drug Administration to pemit the filing of an Abbreviated New Drug Application for an Over-The-Counter (OTC) drug product,Famotidine Orally Disintegrating Tablets 10mg, was received by this office on 07/19/00. It was assigned docket number 00P-1422/CP 1 and it was filed on 07/19/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler
Dockets Management Branch

irma
hna, Ph.D.

To: Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Yamanouchi Pharma
Technologies, Inc.
Raan V. Krishna, Ph.D.
Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304

To: Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Servi
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857